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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/557,997

Applicant(s)

VENKATARAMAN ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,37 and 54-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,37 and 54-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendments and remarks, filed 5/27/05, are acknowledged. Amended claim 36 is acknowledged.

Applicant's arguments, filed 5/27/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 36-37 and 54-72 are herein under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-37 and 54-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 (now line 13) recites the phrase "based on" which is vague and indefinite. It is unclear what parameters and to what degree these parameters must be met so that they are considered to be "based on". Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 37 and 54-72 are also rejected due to their direct or indirect dependency from claim 36.

Applicant states that instant claim 36 has been amended so that this rejection is moot. While claim amendments have been made to clarify the wording on the penultimate line of

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instant claim 36, the issue still occurs on line 13 of this claim. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 54-55, 57, 61-62, 65, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filvaroff et al. (US 6,734,288 B2) in view of Lowe et al. (US 5,770,420).

This rejection is necessitated by amendment.

Filvaroff et al. describe a method of comparing amino acid sequences for matches between a query sequence with a given sequence (first and second data structures) using (tangibly embodied) computer programs ALIGN-2 or NCBI-BLAST-2 (col. 23, lines 9-33; col. 27, lines 30-63) which represent computer readable media. Filvaroff et al. describe using BLAST and FastA sequence alignment (col. 68, lines 15-18) which represents a user providing input into one or more fields, as stated in step (A) of instant claim 36. Filvaroff et al. describe using antigen-complexes (col. 6, lines 5-6; col. 31, lines 29-30; col. 31, lines 39-42; col. 95, lines 62-64). According to the Merriam-Webster online dictionary, "antigen" is defined as a usually protein or carbohydrate substance. According to the Merriam-Webster online dictionary, "carbohydrate" is defined as any of various neutral compounds, such as sugars (or saccharides),

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according to the Merriam-Webster online dictionary. Thus, the antigen-complexes represent monosaccharides or disaccharides of a polysaccharide which is not a nucleic acid, as stated in instant claim 36. Figures 2 (lines 3-4) and 4 (lines 2-3) represent examples of identifiers that include one or more fields as well as values corresponding to the sequence listed, as stated in the preamble of instant claim 36. Filvaroff et al. describe using masking options on repetitive sequences to return a masked query sequence (col. 24, line 30; col. 107, lines 46-55), which represents generating at least one mask based on the values stored in one or more fields of the first data structure, as stated in step (B) of instant claim 36. "Binary operation" is not succinctly defined in the instant specification. As Webster's II New Riverside Dictionary defines "binary" to be composed of two different parts, the calculation of 100 multiplied by X/Y where X is an amino acid score and Y is the total number of amino acid residues in a sequence (col. 23, lines 34-46) represents a type of two part mathematical operation to generate a result, as stated in step (C) of instant claim 36. Tables 2 and 3 demonstrate how to calculate the percent amino acid sequence identity of PRO complexes (col. 23, lines 52-61 and col. 67, lines 1-25). PRO polypeptides may be combined with monosaccharides, disaccharides, and other carbohydrates including glucose, mannose, and dextrans (col. 85, lines 10-15 and 21-31). PRO 355 is a cytotoxic or regulatory T cell associated molecule structurally related to the immunoglobulin superfamily (col. 5, lines 56-67). PRO followed by a number identifies a polypeptide (col. 21, lines 3-7) which represents a numerical identifier, as stated in instant claim 55. The percent identity represents a value corresponding to a property, as stated in instant claims 61 and 62. Figure 2, line 4, lists the MW number which represents the molecular weight of a query sequence, as stated in instant claim 65. "Non-character based field" is not specifically defined in

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the instant specification, but the specification gives examples of values as either a binary or decimal value. Therefore, Filvaroff et al. describe in Figure 2 (line 4) a value in the pI field which is a decimal value or non-character based field, as stated in instant claims 54 and 57.

Filvaroff et al. do not describe comparing at least one result to at least one mask and determining one or more properties of the saccharide, as stated in instant claims 36 and 69.

Lowe et al. describe a comparison on protein sequences of Fuc-TIII and Fuc-TVI which contain saccharides (fucose) in Figures 9a and 9b. In Figure 9a, Lowe et al. show potential glycosylation sites indicated by branched "Y" symbols for Fuc-TIII (top) and FucTVI (bottom) as well as the disaccharide portions of the potential oligosaccharide acceptors (col. 4, lines 9-35) which represent comparisons of saccharides and their locations in the sequences between the two Fuc complexes. In Figure 9a, the "R" denotes the glycoconjugate that displays the disaccharide. In Figure 10, Lowe et al. show a comparison of sequences involving saccharides including glycosylation sites (indicated by branched "Y" symbols. Figure 13 shows matches of comparisons of various saccharide complexes with masking (denoted with "-" marks) as well as masked regions within Fuc-TVI (parts that are not unique to this complex), which represents determining saccharide-complex matches (denoted with "*" marks) by comparing at least one result to at least one mask, as stated in instant claim 36. Lowe et al. describe the process of masking with N-acetylgalactosamine molecules which are attached by an enzyme to the galactose (saccharide) of Fuc α (1,2)Gal linkage (col. 45, lines 1-3). Lowe et al. describe loss of H reactivity or masking of H structures by the enzyme-catalyzed attachment of the N-acetylgalactosamine with cells expressing cell surface glycoconjugates (col. 45, lines 10-21)

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which represents a property of the saccharide-complex, as stated in instant claim 69. Lowe et al. describe modifying cell surface oligosaccharide structure (col. 2, lines 46-50).

Filvaroff et al. state efforts underway by both industry and academia to identify new, native receptor or membrane-bound proteins (col. 2, lines 19-22). Filvaroff et al. identify and characterize novel polypeptides having significant homology to various receptor proteins and glycosylated proteins (col. 3, lines 16-19 and col. 4, lines 29-33 and col. 5, lines 28-50). Filvaroff et al. state receptor molecules have various industrial applications, including pharmaceutical and diagnostic agents (col. 2, lines 11-13). Lowe et al. state glycosylated proteins as tumor-associated antigens are used to identify numerous carcinomas (col. 1, lines 38-42). Lowe et al. state oligosaccharides have been found to exhibit biological activity and used as bacteria receptor sites in diagnosis and identification of specific bacteria (col. 1, lines 38-42 and 54-57). Lowe et al. state that oligosaccharides have influence on the protein or lipid to which they are conjugated as well as oligosaccharide changes in cancerous cells (col. 1, lines 58-67). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to identify receptor proteins, glycosylated proteins and study their roles in organisms via screening methods, as state by Filvaroff et al. (col. 1, lines 24-40, 56-67 and col. 2, lines 19-24 and col. 5, lines 29-50) with result comparisons to glycosylated proteins as well as masks involving saccharides, as stated by Lowe et al. (col. 1, lines Figure 13). The person of ordinary skill in the art would have been motivated to make this modification in order to determine the significant roles in biological functions and changes of glycosylated proteins and receptor proteins involving saccharides linked to cancer and cell differentiation, as stated by Lowe et al. (col. 1, line 64 to col. 2, line 3).

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Thus, Filvaroff et al. in view of Lowe et al. motivate the limitations in instant claims 36, 54-55, 57, 61-62, 65, and 69.

Applicant summarizes part of the previous rejection and state they disagree with the interpretations of Filvaroff et al. regarding "antigen-complex", but do not explain why these interpretations would be considered improper. Applicant argues that Filvaroff et al. do not perform a single analysis of a polysaccharide. While this argument is not found persuasive, due to the interpretation of Filvaroff et al. given above, it is noted that the added prior art (necessitated by amendment) strengthens the idea of saccharide-complex matching. Applicant arguments regarding a method involving monosaccharides or polysaccharides are unpersuasive as the claims had been interpreted broadly and reasonable as described in the rejection. The current arguments are further considered moot with the addition of the Lowe et al. reference. Applicant argues that no analysis was done on polysaccharides. This statement is considered unpersuasive as an antigen-complex was analyzed and has been further supported with the Lowe et al. reference. Applicant argues that the Examiner was improperly importing limitations into the Applicant's disclosure. This statement is found unpersuasive because Applicant's disclosure failed to provide clear and concise definitions of various terms recited in the claims, such that these words were given their broadest and reasonable interpretations. Applicant's arguments are deemed unpersuasive for the reasons set forth above.

Conclusion

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

**MARJORIE A. MORAN
PRIMARY EXAMINER**

Marjorie A. Moran
8/4/05

July 26, 2005